



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SAWATZKI et al.

Serial No: 09/581,520

Filed: June 23, 2000

For: FAT BLEND

Group Art Unit: 1615

Examiner: C. Evans

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REQUEST FOR RECONSIDERATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Official Action of August 13, 2002, in connection with the above-identified application. The period for response to this Official Action has been extended to expire on December 13, 2002, by the filing herewith of a Petition for a One Month Extension of Time and payment of the required fee.

The rejection of claims 1-14 and 16-21 under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. has been carefully considered but is most respectfully traversed on the grounds that the rejection does not establish that the claims are prima facie obvious from the prior art.

In the Official Action it is acknowledged that the DeMichele et al reference does not expressly disclose Applicants' claim to weight percent of the claimed fatty acids but argues that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. In support thereof, it is argued that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation with the citation of *In re Aller*, 105 USPQ 233, 235. However, Applicants most respectfully submit that the "general conditions of a claim", here, the claimed invention is not disclosed in the prior art.

In addition, the Official Action notes that the prior art is different from the claimed invention in that the prior art does not expressly disclose Applicants' claims,

concentrations, however it is stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to manipulate the amounts of the fatty acids in order to optimize the efficacy of the composition. Reference is made to section 2112.01 of the MPEP wherein it is indicated that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by the identical or substantially identical process, a prima facie case of either anticipation or obviousness has been established. It is then concluded that a prima facie case of obviousness has been established. This conclusion misconstrues the teaching of the references as would be appreciated by one of ordinary skill in the art to which the invention pertains and is not based upon the appropriate standard of obviousness taking into consideration as set forth in the MPEP § 2143.

This section of the MPEP states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

More specifically, it is urged in the Official Action that the fat blend of the invention is not inventive since DeMichele discloses a composition comprising an effective amount of several fatty acids including stearidonic acid, eicosapentaenoic acid, gamma-linolenic acid and arachidonic acid. According to the rejection, it would have been obvious to one of ordinary skill in the art at the time of the invention to manipulate the amounts of the fatty acids in order to optimize the efficacy of the composition.

In this context, the Examiner overlooks the following.

It has long been known that polyunsaturated fatty acids play an important role in the nutrition of human beings and in particular in the metabolism of fatty acids. DeMichele depicts in fig. 1 a chart of a pathway showing the elongation and desaturation of the two major families of dietary polyunsaturated fatty acids (PUFA).

Applicants note that one of ordinary skill in the art would appreciate that there are numerous nutritional compositions which have been proposed so far which are supplemented with these PUFAs belonging to the n-3-series and the n-6-series.

In addition it has been known for a long time that these PUFAs can exhibit specific desirable effects. The DeMichele reference is a typical publication of this kind. The nutritional product there proposed shall provide desirable effects when fed to pulmonary patients.

The nutritional composition taught by DeMichele contains almost all PUFAs which participate in the δ -desaturase-pathway as described in fig. 1 of DeMichele. In other words, the DeMichele composition contains all PUFAs of the n-3-series, i.e. α -linolenic acid, stearidonic acid, eicosapentaenoic acid and docosahexaenoic acid and this would be understood by one of ordinary skill in the art to which the invention pertains. Furthermore, it would be understood that the nutritional composition or product, respectively, contains three PUFAs of the n-6-series, i.e. linolenic acid, gamma-linolenic acid and arachidonic acid.

It is not the basic teaching of DeMichele to use these PUFAs but to use them in a certain weight range. There exist numerous publications describing compositions in which these PUFAs are used in other weight ranges. The reason for this is that the PUFAs can exhibit specific effects depending on the composition of the PUFAs. In this

context a copy of the article "Dietary Fatty Acids and the Immune System"; Calder, PC; Nutrition Reviews, Vol. 56, No. 1 (S70 to S83) is enclosed herewith confirming the above understanding by one of ordinary skill in the art. By looking to the list of literature contained in said article it becomes quite evident that the PUFAs can be used for numerous purposes and have been investigated quite a lot.

Enclosed herewith is a further article "omega 3 polyunsaturated fatty acids, inflammation and immunity"; Calder PC; World Rev. Nutr. Diet 2001; 88:109-16. This article discusses more than 25 studies which have been designed and performed to find the most effective quantities of PUFAs with respect to the immune modulation.

This publication makes clear that each single fatty acid of the n-3-series and the n-6series has specific immunologic effects and that the concentrations and mixing ratios play an important role.

A great part of the publications and compositions, respectively, known so far teach to use all of the PUFAs or a great number of the PUFAs in different weight ratios and concentrations. This fact would be fully appreciated by one of ordinary skill in the art to which the invention pertains. As clearly established by the above, DeMichele is representative of these publications.

The other part of the publications or compositions, respectively, concern the most important PUFAs and therefore those which are most commonly present, such as ARA (arachidonic acid), ALNA (α -linolenic acid) and LNA (linolenic acid).

In contrast thereto the present invention is not concerned with the known re-mixing all of the PUFAs or most of the PUFAs in a new weight ratio. The invention rather teaches to put emphasis on very specific PUFAs which are normally more or less "neglected" in the prior art.

The inventors have surprisingly found that stearidonic acid plays an important role and that the content thereof in the fat blend should be raised as compared to the fat blends or nutritional products, respectively, known so far. In other words, according to the present invention the stearidonic acid is present in an amount which is only a little bit lower than the amount in which the other PUFAs of interest (gamma-linolenic acid and eicosapentaenoic acid) are present and this is clearly not suggested by the prior art. Obvious to try is not the standard of obviousness under 35 USC 103(a).


As would be appreciated by one of ordinary skill in the art. The above is in contrast to the teaching of DeMichele which in no way suggests the presently claimed invention to one of ordinary skill in the art, The stearidonic acid there employed is present in an amount which is much less than the amounts of the other fatty acids employed. Where is there any motivation to increase this amount in accordance with the present invention? Applicants' specification may not be used as such a teaching or motivation. In re Fritch, 23 USPQ 1780, 1784 (Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

Moreover, in this context, Applicants wish to emphasize that it is not sufficient just to raise the amount of stearidonic acid. In addition, the amounts of the other PUFAs of interest (gamma-linolenic acid eicosapentaenoic acid) which are present together with stearidonic acid is important. It is nowhere disclosed in the literature that these three fatty acids show some kind of "interpendance". In this context, Applicants most respectfully direct the Examiner's attention to the introductory part of the description of the present application where it is pointed out that it has surprisingly been found that the eicosanoid metabolism of arachidonic acid can be effectively and optimally influenced by administration of the polyunsaturated fatty acids gamma-linolenic acid, eicosapentaenoic acid and stearidonic acid in a specific, balanced portion one to another.

As a conclusion it can be stated that the claimed weight-percent of the claimed fatty acids are not disclosed or suggested in the prior art as represented by DeMichele. Contrary to the assertion in the Official Action, the amounts of the fatty acids as taught by DeMichele are not just manipulated in order to optimize the efficacy of the composition. Moreover, there is no motivation to one of ordinary skill in the art to lead one to make the necessary selections to arrive at the claimed invention. The composition of the invention rather specifically influences the eicosanoid metabolism of arachidonic acid by incorporating three specific PUFAs in a balanced portion to one to another in the composition of the present invention. The rejection has not established that the DeMichele reference makes the claimed invention prima facie obvious. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further information submitted herewith, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,
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